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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,533	03/08/2002	Alfred Jann	112843-035	5939

7590

08/26/2003

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/979,533

Applicant(s)

JANN ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 7-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

Art Unit: 1651

The application should be reviewed for errors. Error occurs, for example, in the spelling of "galacto-oligosaccharides" in claim 23.

The election without traverse filed 6/30/03 is acknowledged. Claims 6 and 22-24 are being considered on the merits.

Claims 1-5 and 7-21 are withdrawn from consideration.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 22-24 are vague, indefinite and confusing in that the extent of "increase" of "insulin sensitivity" is not set forth with any particularity. Is 0.0001%, 0.1%, 1%, 10%, 50% increase intended? Claim 24 is vague and indefinite in the use of "rich" and "poor" with respect to the fatty acid content. These terms are relative term which render the claims indefinite. The term "increase", "rich", "poor" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 23 encompasses an improper Markush grouping because of the use of "or" and "and". Conjunctive rather than alternative language should be used (e.g. selected from the group consisting of A, B, AND C). The claim as drafted does not follow this form. See MPEP 2173.05(h)(a). Claim 23 is confusing in that inulin is a fructo-oligosaccharide.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1651

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mitsuhashi *et al.*.

The claim is directed to a process of increasing insulin sensitivity in a mammal by the step of administering a composition comprising dextran.

Mitsuhashi *et al.* disclose a process of administering a composition comprising dextran to mammals for the purpose of promoting the growth of intestinal *Bifidobacterium*. The inherent result of this administration is an increase in insulin sensitivity in the mammal at least to some extent (See, e.g., Examples 9 and 11).

Claims 6 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Novak '720 or Novak '873 or Toulmin '349 or Toulmin '799.

The claim is directed to a process of increasing insulin sensitivity in a mammal by the step of administering a composition comprising dextran, including dextran having a molecular weight above about 500,000.

Each of Novak '720 or Novak '873 or Toulmin '349 or Toulmin '799 discloses a process of administering a composition comprising dextran to mammals. The inherent result of this administration is an increase in insulin sensitivity in the mammal at least to some extent. See, e.g., Novak '720 (col. 2 and col. 3, lines 25-60) or Novak '873 (Col. 1, lines 51-70; Example 2) or Toulmin '349 (col. 2 and col. 4) or Toulmin '799 (col. 2, Examples I, II and IV).

Claims 6 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi *et al.*.

As noted *supra*, Mitsuhashi *et al.* disclose a process of administering a composition comprising dextran to mammals for the purpose of promoting the growth of intestinal *Bifidobacterium*. A result of this administration is an increase in insulin sensitivity in the mammal at least to some extent (See, e.g., Examples 9 and 11 and page 5, lines 37-43), since it

Art Unit: 1651

has as an effect the prevention of diabetes. In addition the reference discloses that the addition of certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides is beneficial to enhance the promotion of *Bifidobacterium* (See, e.g., Abstract), which further enhances the desired effect of increasing insulin sensitivity. The reference also discloses that that the nutritional compositions containing dextran also comprise lipid sources "rich" in unsaturated fatty acids, such as unsaturated fatty acids *per se*, which are naturally "poor" in saturated fatty acids (See, e.g., page 3, lines 14-16).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Mitsuhashi *et al.* of administering compositions comprising dextran to mammals by adding certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides and/or unsaturated fatty acids to the compositions for the expected benefits of providing a compositions which is more complete nutritionally and which has the effect of increasing the *Bifidobacterium* flora and of preventing diabetes by increasing insulin sensitivity at least to some extent.


Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651